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FISH & RICHARDSON PC
P.O. BOX 1022
MINNEAPOLIS, MN 55440-1022

EXAMINER	
KHOLDEBARIN, IMAN KENNETH	
ART UNIT	**PAPER NUMBER**
3709	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/669,101	LEVENSON, RICHARD	
	Examiner	Art Unit	
	I Kenneth Kholdebarin	3709	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) 30 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-40 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 09/23/2003.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 25, 27, 29, 32 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 25, 27, 29, 32 and 33 are recites the limitation "the recorded images" in line 1 and line 2. There is insufficient antecedent basis for this limitation in the claim.

Claims 26 is identical to claim 30, Claim 30 is redundant so that it should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 1- 10, 13-19, 22, 34 and 37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Arndt (2004/0081621).

Re Claim 1: Arndt discloses a method comprising:

illuminating (S) a sample (3) to cause the sample to emit radiation (L) wherein the sample comprises deep tissue supporting a target compound, and wherein the emitted radiation comprises mission from the target compound and emission from one or more other components in the sample;

spectrally filtering (23) the emitted radiation with each of a plurality of different spectral weighting functions,

storing an image of the spectrally filtered radiation for each of the spectral weighting function and processing the stored images to construct a deep tissue image of the sample in which signal from the other compounds in reduced relative to signal from the target compound (See Fig. 1 and paragraph [0050, 0051]).

Re Claims 2-6 and 8: Arndt discloses the sample comprising the deep tissue is living organism, an animal, mammal, mouse, being an internal organ of the living organism and subdermal tissue (See fig.1, paragraph [0047]).

Re Claim 7 and 40: Although Arndt is silent with respect to deep tissue lies within about 2 mm or more of the living organism as recited in claim 7, and the 2 cm field of view as recited in claim 40, it is believed to be inherent to have the deep tissue of an internal organ such as a human or a mouse lying about 2 mm or more of the living organism, and having 2 cm of field of view the detector.

Re Claims 9 and 10: Arndt discloses the emission from the other components of the sample comprises auto fluorescence from tissue overlying the deep tissue as recited in claim 9 and from one or more layers of tissue in the sample different from a player of tissue comprising the deep tissue as recited in claim 10, since the luminescent light which contains auto fluorescence excited by the irradiation of the sample that contains the overlaying of the deep tissue and the layers of tissue in the sample are detected by a detector and the auto-fluorescent was understood to be the reflection of the fluorescent light from an object, (See paragraph [0009]).

Re Claims 13-15: Arndt discloses where the target compound is a green, yellow or red fluorescent protein bound to at least a portion of the deep tissue / different marker could be used to interact with different tissues. If use of the green fluorescent protein was known at the time of the invention therefore yellow or red fluorescent marker were possible to be used. (See paragraph [0048] and the table).

Re Claim 16: Arndt discloses where the emission from the target compounds is fluorescence / earlier discussed the fluorescent radiation returning from the object which contains the target as well (See paragraph [0009]).

Re Claims 17 and 18: Arndt disclose at least some or all of the spectral weighting function corresponds to particular wavelength (See paragraph [0034]).

Re Claim 19: Arndt discloses the spectral weighting functions correspond to sinusoidal weighting of multiple wavelength bands (See fig.10 and paragraph [0056]).

Re Claim 22: Arndt disclose the spectral filtering using a filter wheel (37) containing pluralities of band pass filters (See paragraph [0057] and [0058]).

Re Claim 34: Arndt disclose the different spectral weighting function comprises at least four spectra weighting functions since D1-D12 has the potential of generating 12 different wavelengths (spectra weighting function). (See paragraph [0049]).

Re Claim 37: Arndt disclose an apparatus comprising a sample holder (5) comprising deep tissue, wherein the deep tissue supports a target compound and illumination source (D1-D12) configured to illuminate the sample (3) to cause it to emit radiation (L), wherein the emitted radiation comprises emission from the target compound and emission from one or more other components in the sample, and imaging system

configured to image the emitted radiation to a detector (27); a tunable spectral filter (17) configured to spectrally filter the emitted radiation with each of a plurality of different spectral weighting functions, a detector (27) configured to store an image of the spectrally filtered radiation for each of the spectral weighting function; and a electronic processor (image processing not shown see paragraph [0051] line 3-5), configured to process the store images to construct a deep tissue image of the sample in which signal from the other compounds is reduced relative to signal from the target compound (See paragraph [0049]~[0051]).

Re Claim 38: Arndt disclose wherein the sample holder is configured to hold an animal (3) (See Fig. 1).

Re Claim 39: Arndt discloses wherein the imaging system has a demagnification (21) greater than or equal to 1 (See Fig. 1, also paragraph [0050] line 3).

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 35-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Wolleschensky, (US 6,891,613).

Re Claim 35: Wolleschensky discloses a method of plurality of images of spectrally filtered radiation emitted from a sample in response to an illumination, wherein the sample comprises deep tissue supporting a target /dyes, compound and the emitted radiation comprises emission from the target compound and emission from one or more other components in the sample and each image corresponds to a different spectral weighting function / different wavelength, and processing the images of the spectrally filtered radiation to construct a deep tissue image of the sample in which signal from the other compounds is reduced relative to signal from the target compound (See fig. 12 and 13(a-d) as well as col.10 line 25-30 and 50-60, also fig. 4;col.7 line 13-29).

Re Claim 36: Wolleschensky disclose an apparatus / an arrangement that contains memory to record and use the recorded data which stores a program that causes a processor to perform the method of plurality of images of spectrally filtered radiation emitted from a sample in response to an illumination, since Wolleschensky has a computer (computer of fig. 10) having the aforementioned conventional feature, wherein the sample comprises deep tissue supporting a target /dyes, compound and the emitted radiation comprises emission from the target compound and emission from one or more other components in the sample and each image corresponds to a different spectral weighting function / different wavelength, and processing the images of the spectrally filtered radiation to construct a deep tissue image of the sample in which signal from the other compounds is reduced relative to signal from the target compound. (See fig 13(a-d) as well as col.10 line 25-30 and 50-60, and fig. 3 and 4;col.7 line 13-29)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt ('621) in view of Crowley (6,289,229). The teachings of Arndt have been discussed above.

However, Arndt fails to disclose or fairly suggest target compound to be bound to fluorescent probe to at least a portion of the deep tissue,

Crowley teaches the use of fluorescent probe in study in vivo. These probe made out of materials sensitive to indicators that have been designed to fluoresce or change color, as observed by spectrographic analysis methods. (See col.2 line 55-60).

Therefore, in view of Crowley, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the optically readable probes that have specific affinity to one proteins or other chemicals as a method to bound to a portion of

tissue in vivo of Arndt, in order to performs specific detection and analysis of biological analytic in vivo using a simplified, low cost set of components.

9. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt ('621) in view of Madden (2005/0171434). The teachings of Arndt have been discussed above.

Claim 12: However, Arndt fails to disclose or fairly suggest target compound to be bound to quantum dot to at least a portion of the deep tissue,

Madden teaches the use of quantum dot as a type of chromophores with excitation and emission wavelengths in the red and near infrared spectrum. Use of quantum dot will help to maximizes tissue penetration and minimizes absorption by physiologically abundant absorbs such as hemoglobin and water within a tissue. (See paragraph [0028] and [0029]).

Therefore, in view of Madden, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the quantum dot, as infrared chromophorse, to bound to the biological tissue for examining and obtaining a respond of the target inside a deep tissue of Arndt, in order to determine a number of indicia, including tracking the localization of the imaging construct in the subject over time and assessing changes in the level of the imaging construct in the subject over time.

10. Claims 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt ('621) in view of Treado (US 6,954,667). The teachings of Arndt have been discussed above.

Re Claim 20 and 21: However, Arndt fails to disclose or fairly suggest spectral filtering comprises using a liquid-crystal, tunable optical filter.

Treado teaches the use of liquid-crystal as optical filter(57). (See col.5 line 21-30). Also treado teaches the use of interferometric optical filter to detect the monochromatic lights used to illuminate in vivo examining.

Therefore, in view of Treado, it would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the liquid –crystal tunable filter instead of the filter (17) disclosed by Arndt, in order to distinguished different spectral weighting functions corresponded to different wavelength.

11. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt ('621) in view of Cronin (US 2003/0081204). The teachings of Arndt have been discussed above.

Re Claim 23: However, Arndt fails to disclose or fairly suggest the method that stored image comprises an intensity value of each of multiple pixels,

Cronin teaches intensity data which is recorded for each 2D spatial pixel at each of a number of wavelengths (See Paragraph [0005]).

Therefore, in view of Cronin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have stored image which comprises multiple pixels in order to determine the multiple stain / target, concentration present in the sample.

12. Claims 24-27 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt ('621) in view of Pettipiece (US 6,051,835). The teachings of Arndt have been discussed above.

Re Claims 24-27 and 29: However, Arndt fails to disclose or fairly suggest the method of constructing the image based on weighted superposition of signals or using at least one emission spectrum from the components in the sample or the calculation a reminder spectrum for each pixel,

Pettippiece teaches the method of constructing the image by using the emission spectrum/ the reflection from the sample and the target, determined from each pixel (See col. 5 lines 49-50 and 60-67).

Therefore, in view of Pettippiece, it would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the method of using the weighted signals emitted from the object that contains the target and the information from the pixel of the stored data to use as weighted superposition of signals to the image

construction step of Arndt, in order to efficiently distinguish the dyes used to identify the target within the object for constructing the image.

Re Claims 31-33: However, Arndt fails to disclose or fairly suggest constructing the image where the sample supports multiple target compounds and use of the recorded images / data and emission spectra for the target compounds and at least one emission spectrum for the other components in the sample,

Pettippiece teaches the method of constructing the image by using the emission spectrum/ the reflection from the sample and the target, and the use if each pixel representing the stored image (See col. 5 lines 49-50 and 60-67).

Therefore, in view of Pettippiece, it would have been obvious to one of ordinary skill in the art at the time the invention was made to exploit the spectra and information of each pixel obtained from the reflected data of the target compounds to construct the image disclosed by Arndt, in order to develop an image that shows the target compounds distinguished from the other part of supporting tissue.

13. Claim 28, as understood, is rejected under 35 U.S.C. 103(a) as being unpatentable over Arndt, as modified by Pettippiece as applied to claim 27 above, and further in view of Cronin (US 2003/0081204).

The teaching of Arndt modified by Pettippiece has been discussed above.

However, the teachings of Arndt modified by Pettippiece fails to disclose or fairly suggest the method of constructing the image by solving at least one component of a matrix equation in which one matrix is based on the stored images and another matrix is based on the emission spectra,

Cronin teaches, measuring the intensity of the spectral response for each spectra A_k as an element of matrix representing the response to the broadband illumination with a filter corresponding to the K spectra. (See paragraph [0017] and paragraph [0019]).

Therefore, in view of Cronin, it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the method of calculating the emission spectra as modified by Pettippiece by creating the matrix containing each spectra to construct the image by using the element of matrix as ~~thought~~ taught by Cronin in order to analysis of the data collected from the reflection of the emission spectra of the object.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicants disclosure. Cabib discloses method for simultaneously measuring the spectral intensity as a function of wavelength of all the pixels of a two-dimsional scene; Pearlman discloses tissue characterization based on impedance images and on impedance measurements,

Georgakoudi discloses system and methods of fluorescence; reflectance and light scattering spectroscopy for measuring tissue characteristics; Al-Ali discloses noninvasive muit-parameter patient monitor; Fine discloses method and system for use in non-invasive optical measurement; Kanayama discloses living body information measuring apparatus.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to I. Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on 8 am to 4 pm Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jong-Suk (James) Lee can be reached on 571-270-1341. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IKK
I. Kenneth Kholdebarin
November 12, 2006

JONG SUK LEE
SUPERVISORY PATENT EXAMINER